K120375

Benlan™
MED-RX® Patient Delivery Sets

SECTION 5 - 510(K) SUMMARY

Date of Summary: February 3, 2012

JUN 28 2012

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Official Contact: Cheryl Brown – QA / RA Manager

Proprietary Name: MED-RX® Patient Delivery Set
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set, 880.5440 Intravascular Administration Set.
Class: Class II
Product Code: FPA
Predicate Device: Liebel-Flarsheim Optistar MR Injector System→ Y-Tubing Set (K984088)

Device Description

The MED-RX® Patient Delivery Sets each consist of a male luer lock, two female luer locks, 3 tubing pieces, and either a dual check valve, a single check valve, or a Y-connector. The tube is made of polyvinyl chloride (PVC). The total length of the sets varies from 18" to 86" and is also available in a coiled configuration. The MED-RX® Patient Delivery Sets are provided sterile and are not to be resterilized.

Indications for Use

The MED-RX® Patient Delivery Set is to be used in the injection of contrast agents and flushing solutions for the purpose of enhancing diagnostic images.

Substantial Equivalence

The information provided in the premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed MED-RX® Patient Delivery Sets are substantially equivalent to the Liebel-Flarsheim Optistar Y-Tubing Set (K984088). Both devices have the same intended use for injection of contrast agents and flushing solutions for the purpose of enhancing diagnostic images. The product configurations are identical between the proposed device and the predicate.

> *NOTE: The predicate device upon which to determine substantial equivalence is the Y-tubing set included as a sterile disposable in K984088.*

A comparison of features and principles of operation between the proposed device and predicate device is provided in Table 1 below.

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Table 1: Comparison between MED-RX® Patient Delivery Set and Liebel-Flarsheim Optistar Y-Tubing Set (K984088)

ATTRIBUTE	PROPOSED DEVICE - MED-RX® Patient Delivery Set	PREDICATE DEVICE – Liebel-Flarsheim Optistar Y-Tubing Set (K984088)
General Indications		
Indications for Use	The MED-RX® Patient Delivery Set is to be used in the injection of contrast agents and flushing solutions for the purpose of enhancing diagnostic images.	The Optistar MR is designed to inject MR contrast agents and flushing solutions for the purpose of enhancing diagnostic images of humans.
Disposable	Yes	Yes
Prescription	Yes	Yes
Non-Pyrogenic	Yes	Yes
Intended Environment of Use	Hospital	Same
Material Composition		
Tubing	Polyvinyl Chloride - DEHP free	Medical grade tubing
Components	Medical grade plastics (PVC, LDPE, HDPE, Polycarbonate)	Medical grade plastics
Packaging and Sterilization		
Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide (EO)	Same
Packaging Configuration	Medical grade paper/film pouch	Same
Physical Specifications		
Tubing outer diameter (OD)	0.156"	0.130"
Tubing inner diameter (ID)	0.060"	0.060"
Total set length	18" – 86"	66"
Design Features		
Distal Configuration	Male Luer Lock	Same
Proximal Configuration	Two Female Luer Locks	Same
Y-Site	Dual Check Valve *OR* Single Check Valve *OR* Y-Connector	Dual Check Valve *OR* Single Check Valve *OR* Y-Connector
Y-Leg Tube Configuration	Straight	Straight
Long Arm Tube Configuration	Straight *OR* Coiled	Coiled
Maximum Pressure Rating	400 PSI	Same
Caps	Luer caps	Same

Summary of Differences

There are no significant differences between the proposed MED-RX® Patient Delivery Sets and the predicate device, Liebel-Flarsheim Optistar Y-Tubing Set (K984088). Similarities between the proposed device and the predicate device include indications for use and design configuration. The MED-RX® Patient Delivery Sets and the Liebel-Flarsheim Optistar Y-Tubing Set are sterile, disposable devices, packaged in paper/film pouches and sterilized using ethylene oxide.

Both the proposed MED-RX® Patient Delivery Sets and the predicate device feature two female luer locks on the proximal end of the set, followed by two short Y-leg tubes that meet at either a

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dual check valve, a single check valve, or a Y-connector. The Y-site is followed by one long arm tube that terminates with a male luer lock. Protective luer caps are provided for all luer locks. All proximal and distal components are compatible with standard luer devices, similar to the predicate device. The predicate Liebel-Flarsheim Optistar Y-Tubing Set is available in identical configurations to the predicate device.

Any minor differences between the proposed device and the predicate have been evaluated to have no impact on safety or effectiveness of the MED-RX® Patient Delivery Sets. Therefore the proposed device can be considered substantially equivalent to legally market devices and raises no new issues of safety and effectiveness.

Non-Clinical Test Summary

The MED-RX® Patient Delivery Sets were subject to numerous performance tests including tensile strength, resistance to leakage, particulate contamination, and for chemical requirements. The MED-RX® Patient Delivery Sets have successfully completed all required performance testing following the applicable guidelines of ISO 8536-4: 2010. The MED-RX® Patient Delivery Sets were also tested for natural rubber latex content. Please refer to Table 2.

Table 2: Non-Clinical Test Summary

Test	Standard	Results
Tensile Strength	ISO 8536-4:2010	Withstand 15 N for 15 Seconds, Pass
Resistance to Leakage	As per Benlan internal requirements	Pass
Particulate Contamination	ISO 8536-4: 2010	Samples met contamination index limit
Chemical Requirements	ISO 8536-4:2007 PER Clause 5 & 7	Pass
Natural Rubber Latex Content	Modified Lowry Method	Device does not contain natural rubber latex

Summary of Sterilization

Each MED-RX® Patient Delivery Set is individually packaged using a medical grade breathable coated paper heat sealed to a polypropylene medical grade film and sterilized using ethylene oxide. Please see Table 3 for a summary.

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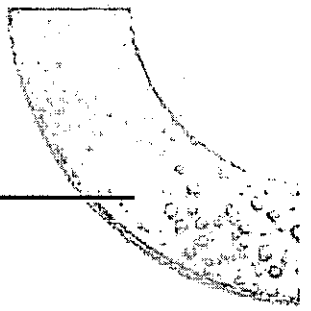

Table 3: Sterilization Summary

Test Description	Standard	Results
Method of Validation	ANSI/AAMI/ISO 11135-1: 2007	Validated to a Sterility Assurance Level of 1×10^{-6}
EO Sterilization Residuals	ISO 10993-7: 2008	Pass
Bacterial Endotoxins	Current edition of ANSI/AAMI ST72	Pass

Summary of Biocompatibility Tests

Biocompatibility testing was successfully completed on sterile finished devices. The MED-RX® Patient Delivery Sets are classified as external communicating devices with limited to prolonged use, indirect blood path contact. A summary of the testing completed and the relevant standards are listed in Table 4.

Table 4: Biocompatibility Test Summary

Standard	Test Description	Results
ASTM F-756-00	Hemolysis Assay – Extract Method	Product code 10-1254T is considered non-hemolytic and passes the test.
ISO 10993-11	Acute Systemic Injection Test	The findings indicate that the requirements of the ISO Acute Systemic Injection Test have been met.
USP 32:2009 <151>	Materials Mediated Rabbit Pyrogen Test	Product code 10-1254T was considered non-pyrogenic.
ISO 10993-10:2002	Intracutaneous Reactivity Test	The requirements of the ISO Intracutaneous Reactivity Test have been met.
ISO 10993-10:2002	Guinea Pig Maximization Sensitization Test	Product code 10-1254T did not elicit a sensitization response.
ISO 10993-5: 2009	ISO MEM Elution with L-929 Mouse Fibroblast Cells (Cytotoxicity)	Product code 10-1254T is considered non-cytotoxic.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
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Ms. Cheryl Brown
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JUN 28 2012

Re: K120375
Trade/Device Name: MED-RX® Patient Delivery Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 15, 2012
Received: June 20, 2012

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE

510(K) Number (If Known): K 120375

Device Name: MED-RX® Patient Delivery Set

Indications For Use:

The MED-RX® Patient Delivery Set is to be used in the injection of contrast agents and flushing solutions for the purpose of enhancing diagnostic images.

Prescription Use:	✓	AND/OR	Over-the-Counter Use	N/A
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/28/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120375